Schuster, Dave

From: Nixon, Gerry M.
Sent: Wednesday, April 30, 2003 11:30 AM
To: Schuster, Dave
Cc: King, Valerie A.; Koller, Debbie; Werley, Michael S
Subject: RE: Input to Master Plan Template

Dave,

I would suggest that the Investigator's Brochure (IB) still belongs in Clinical because it is apparently needed for those studies. It is true that someone in Non-Clinical has been writing it (Debbie, Mike, etc.), but I do not believe that it is used for any non-clinical work. Debbie or Mike may help with defining predecessors and timelines for the IB.
— waiting for reply from Debbie &/or Mike
The Define Study Objectives and Develop Protocol Summary lines have been in the Clinical schedules for a long time, I believe. There are similar lines in the non-clinical portions of the schedule, but I believe that these Valerie mentions refer to setting up clinical studies. If they are not needed, that is a Clinical call.

As we discussed, there are lines in the non-clinical portions referring to requesting cigarettes and getting them made for non-clinical testing, and there should be similar lines in the Clinical portions, as there is some preparation time and effort needed before the test cigarettes appear at the testing facility.

Gerry

-----Original Message-----
From: Schuster, Dave
Sent: Wednesday, April 30, 2003 10:55 AM
To: Nixon, Gerry M.
Subject: Input to Master Plan Template

Gerry,
I have Val's updates and she has a note that says Clinical does not write Investigator's Brochure, Define Study Objectives and Develop Protocol Summary and therefore believes that it should belong to Non-Clinical. What do you think; should this be in your area? Of course, my question is why has this not been discussed before now?

Dave

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